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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,638	ROUANET ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12/15/03, 7/19/04, 10/19/04, 1/6/05, 4/6/05, 7/27/05, 11/21/2005

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) 1-25 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/19/04, 1/6/05, 4/6/2005, 7/27/2005, 11/21/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a method of treating or preventing breast cancer by administering 4-hydroxy tamoxifen, classified in class 514, subclass 736, for example.

II. Claims 26-38, drawn to a composition for percutaneous administration comprising 4-hydroxy tamoxifen and at least one penetration enhancer, classified in class 514, subclass 736, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process can be practiced with a materially different product. For example, breast cancer can be treated by administering tamoxifen itself.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination

purposes as indicated is proper. It is noted that while the searches of Groups I and II may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group II, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Group I. Conversely, in searching Group I, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Stephen Bent on April 20, 2006, a provisional election was made without traverse to prosecute the invention of Group II, claims 26-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claims 1-38 are pending in the application, with claims 1-25 being withdrawn as drawn to a non-elected invention. Accordingly, claims 26-38 are being examined on the merits herein.

Oath/Declaration

Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over each applicant's signature providing a complete post office address of each applicant is required.

Claim Objections

Claim 31 is objected to because the word "vehicle" is spelled incorrectly as "vehicule" in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,904,930 to Fischer et al, issued May 18, 1999.

Fischer et al. teaches a transdermal system comprising a tamoxifen derivative (see abstract, in particular), and thus teaches a pharmaceutical composition for percutaneous administration. Fischer et al. teaches that 4-hydroxytamoxifen is a suitable candidate for topical administration, for example for the treatment of tumors (see column 1, lines 10 through column 2, line 15, in particular.) Fischer et al. further teaches that vitamin E of vitamin E derivatives can be provided in the composition to increase permeation of the skin (penetration enhancer) (see column 2, lines 33-55, in particular.) Fischer et al. exemplifies a transdermal system comprising 4-hydroxytamoxifen and vitamin E (see example 6, in particular), and thus teaches a composition for percutaneous administration comprising 4-hydroxy tamoxifen and a penetration enhancer, as recited in claim 26.

Regarding claim 27, Fischer et al. exemplifies the composition having a microporous membrane, and thus teaches a patch as recited in the claim.

Claims 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by the article "Cutaneously Applied 4-hydroxytamoxifen is not Carcinogenic in Rats" by Sauvez et al, Carcinogenesis, Vol. 20, No. 5, 1999, pages 843-850, as evidenced by Chapter 44 of Remington: The Science and Practice of Pharmacy, 20th ed, 2000, pages 836-857, entitled "Medicated Topicals" by Lawrence H. Block.

Sauvez et al. teaches that 4-hydroxytamoxifen is not carcinogenic in rat and reduces the incidence of spontaneous mammary and hypophyseal tumors (see abstract, in particular.) Sauvez et al. teaches that the 4-hydroxytamoxifen is applied cutaneaously, and that the composition comprises a solution of 4-hydroxytamoxifen in ethanol/water (see page 843, right hand column, Materials and Methods section.) Accordingly, Sauvez et al. teaches a pharmaceutical composition for percutaneous administration comprising 4-hydroxy tamoxifen in an ethanol/water solution.

Sauvez et al's teaching of the enthanol/water solution also constitutes a teaching of a penetration enhancer, as evidenced by the teachings of Block. Block teaches that water and alcohols such as ethanol are penetration enhancers in medicated topical compositions (see page 842, Table 44-4, in particular.)

Thus, the 4-hydroxy tamoxifen solution in ethanol/water as taught by Suarez et al. meets the limitation of being a composition comprising 4-hydroxy tamoxifen and a penetration enhancer, as recited in claim 26.

Regarding claim 27, Suarez et al. teaches the hydroalcoholic solution as recited in the claim.

Claims 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, as evidenced by Chapter 44 of Remington: The Science and Practice of Pharmacy, 20th ed, 2000, pages 836-857, entitled "Medicated Topicals" by Lawrence H. Block.

Mauvais-Jarvis et al. teaches a precutaneously administrable drug of the hydroalcoholic type comprising 4-hydroxytamoxifen (see abstract, column 2, lines 25-35 and column 3, lines 30-45, in particular.) Mauvais-Jarvis et al. further exemplifies the composition comprising ethyl alcohol and water (see column 3, lines 30-45, in particular.)

Mauvais-Jarvis et al's teaching of the ethanol/water solution also constitutes a teaching of a penetration enhancer, as evidenced by the teachings of Block. Block teaches that water and alcohols such as ethanol are penetration enhancers in medicated topical compositions (see page 842, Table 44-4, in particular.)

Thus, the 4-hydroxy tamoxifen solution in ethanol/water as taught by Mauvais-Jarvis et al. meets the limitation of being a composition comprising 4-hydroxy tamoxifen and a penetration enhancer, as recited in claim 26.

Regarding claim 27, Mauvais-Jarvis et al. teaches the hydroalcoholic solution as recited in the claim.

Regarding claim 28, Mauvais-Jarvis et al. exemplifies a composition comprising a hydroalcoholic composition comprising the 4-hydroxytamoxifen, a penetration enhancer (water and ethyl alcohol), an aqueous vehicle (water), an alcoholic vehicle (ethyl alcohol), and a gelling agent (Carbopol 934) (see column 3, lines 30-40, in particular.) Accordingly, Mauvais-Jarvis et al. teaches the composition of the claim. Regarding claim 29, Mauvais-Jarvis et al. exemplifies the composition having triethanolamine (neutralizing agent) (see column 3, lines 30-40, in particular.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, as evidenced by Chapter 44 of Remington: The Science and Practice of Pharmacy, 20th ed, 2000, pages 836-857, entitled "Medicated Topicals" by Lawrence H. Block, as applied for claims 26-29 above, and further in view of DE 3836862 A1 to Gunther et al, published May 3, 1990.

Mauvais-Jarvis et al. is applied as discussed for claims 26-29 above, and teaches a hydroalcoholic composition for percutaneous administration comprising 4-hydroxytamoxifen. Mauvais-Jarvis et al. further teaches that the hydroalcoholic gel comprises various excipients required for enabling percutaneous penetration to take place (see column 3, lines 10-40, in particular.)

Regarding claim 31, Mauvais-Jarvis et al. exemplifies a composition comprising 0.15 g (0.15%) of 4-hydroxy tamoxifen, 50 mL of 95% ethyl alcohol, a quantity of water,

and 1 g (1%) of carbopol 934 (gelling agent) (see column 3, lines 30-40, in particular), and thus teaches a composition having amounts of ingredients (a) and (c)-(e) that are close to and/or overlap with the ranges recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the hydroalcoholic gel composition, according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Mauvais-Jarvis et al. does not specifically teach that the composition comprises a penetration enhancer that is a fatty acid ester, as recited in claim 30. Mauvais-Jervais et al. also does not specifically teach the composition comprising isopropyl myristate as recited in claim 31.

Gunther et al teaches a composition for transdermal administration of steroid hormones comprising a fatty acid ester (see abstract, in particular), as recited in claim 31. Gunther et al. teaches that fatty acid esters ensure adequate penetration of the active ingredient through the skin for therapy, and that a preferred fatty acid ester is isopropyl myrisate (see specification, first page, in particular), as recited in claim 31.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the isopropyl myristate of Gunther et al. in the percutaneous composition of Mauvais-Jarvis et al, because Mauvais-Jarvis et al. teaches that the composition comprising the 4-hydroxy tamoxifen steroid composition comprises ingredients to enable percutaneous penetration, and Gunther et al. teaches that the isopropyl myristate ensures percutaneous administration of steroids. Thus, one of ordinary skill in the art would have been motivated to combine the isopropyl myristate into the composition of Mauvais-Jarvis et al, with the expectation of providing a percutaneous formulation that provides suitable penetration of the 4-hydroxy tamoxifen.

Regarding the amount of the isopropyl myristate provided, as recited in part (e) of claim 31 and in claim 32, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the isopropyl myristate provided in the composition, according to the guidance provided by Mauvais-Jarvis et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 32, it is noted that Mauvais-Jarvis et al. exemplifies a composition comprising 4-hydroxy tamoxifen in an amount of 0.15g (0.15%), which is considered to meet the limitation of being "about" 0.5% by weight, as recited in the claim (see column 3, lines 10-40, in particular.) Gunther teaches that concentration of active ingredient of from 0.2 to 20 weight percent can be provided by utilizing the fatty acid ester penetration enhancers (see first page, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 4-hydroxy tamoxifen provided in the composition, according to the guidance provided by Mauvais-Jarvis and the penetration enhancement teachings of Gunther, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 34, Mauvais-Jarvis et al. exemplifies the composition comprising 95% ethyl alcohol in an amount of 50 ml (see column 3, lines 10-40, in particular), which is close to and/or overlaps with the amount as claimed. Regarding claim 36, Mauvais-Jarvis et al. teaches the composition having Carbopol 934 (gelling agent), a polyacrylic acid, in an amount of 1.5 g (1.5%) (see column 3, lines 10-40, in particular), which meets the limitation of the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of ethyl alcohol and/or gelling agent provided in the composition,

according to the guidance provided by Mauvais-Jarvis et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Clams 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, as evidenced by Chapter 44 of Remington: The Science and Practice of Pharmacy, 20th ed, 2000, pages 836-857, entitled "Medicated Topicals" by Lawrence H. Block, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 30-34 and 36 above, and further in view of U.S. Patent No. 5,720,963 to Walter P. Smith, issued February 24, 1998.

Mauvais-Jarvis et al, as evidenced by Block, in view of Gunther et al, as applied as discussed for claims 30-34 and 36 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising 4-hydroxy tamoxifen.

Mauvais-Jarvis et al. also exemplify a composition comprising an aqueous vehicle in an amount that is close to and/or overlaps with that recited in claim 25. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the

aqueous vehicle provided in the composition, according to the guidance provided by Mauvais et al. and Gunther et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The references do not specifically teach providing an aqueous vehicle that is a phosphate buffered solution, as recited in claim 35, or that comprises the specific neutralizing agents as recited in claim 37.

Smith teaches topically applied treatments for skin, which can comprise gels (see abstract, in particular.) Smith teaches that topical treatments can be pH adjusted to within a desired range and may be buffered with buffers such as trimethylolaminomethan (tromethane) or phosphate buffer (see column 32, lines 20-30, in particular), as recited in claims 35 and 37.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the buffers of Smith in the hydroalcoholic gel of Mauvais-Jarvis et al and Gunther et al, because Mauvais-Jarvis and Gunther et al teach the composition is applied percutaneously (topically), and Smith teaches the buffers can be provided to maintain a desired pH of the a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the buffers of Smith in the

composition of Mauvais-Jarvis et al. and Gunther et al, with the expectation of maintaining suitable pH of the composition for topical application.

Regarding the specific amount of the tromethane provided, as recited in claim 37, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the tromethane provided in the composition, according to the guidance provided by Mauvais-Jarvis et al, Gunther et al. and Smith, to provide a composition having desired properties, such as a desired pH. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,919,937 to Mauvais-Jarvis et al, issued April 24, 1990, as evidenced by Chapter 44 of Remington: The Science and Practice of Pharmacy, 20th ed, 2000, pages 836-857, entitled "Medicated Topicals" by Lawrence H. Block, in view of DE 3836862 A1 to Gunther et al, published May 3, 1990, as applied to claims 30-34 and 36 above, and further in view of U.S. Patent No. 6,013,270 to Hargraves et al, issued January 11, 2000.

Mauvais-Jarvis et al, as evidenced by Block, in view of Gunther et al, as applied as discussed for claims 30-34 and 36 above, and teach a hydroalcoholic gel composition for percutaneous administration comprising 4-hydroxy tamoxifen.

The references do not specifically teach that the composition is packaged in a unit dose packet of a multiple dose container with a metered pump, as recited in claim 38.

Hargraves et al. teaches a skin care kit having a skin care composition contained within a dispenser (see abstract, in particular.) Hargraves et al. teaches that the dispenser can comprise a metered pump that an provide multiple doses and is suitable for dispensing skin care compositions such as for medical applications and body care applications (see column 14, line 45 through column 20, line 15, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the dispenser of Hargraves et al. to dispense the composition of Mauvais-Jarvis et al. and Gunther et al, because Mauvais et al. and Gunther et al. teach a medical composition for percutaneous application (topical application), and Hargraves et al. teaches the dispenser dispenses topical compositions, such as medical compositions. Thus, one of ordinary skill in the art would have been motivated to provide the dispenser for the composition of Mauvais-et al. and

Gunther et al, with the expectation of providing a device suitable for the dispensing of the topical composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER